ELEKTA

510(k) Summary K121663

Nov 14, 2012

DEC 0 5 2012

Trade/Device Name:	**Clarity®**
Common Name:	Patient positioning system, ultrasound
Regulation/Classification:	Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code IYE) Radionuclide radiation therapy system (21 CFR 892.5750, Product Code IWB) Radiation therapy simulation system (21 CFR 892.5840, Product Code KPQ)
Regulatory Class:	Class II
Review Panel:	Radiology
Submitter/Manufacturer:	Elekta Ltd.
Establishment Registration No:	3004747535
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Contact:	Tony Falco, PhD

Introduction

This 510(k) Summary has been prepared in accordance with 21 CFR 807.92. It summarizes device safety and effectiveness information to provide an understanding of the basis for a determination of substantial equivalence.

Predicate Device Information

Clarity® is substantially equivalent to the following legally marketed devices in the United States:

- *Clarity® OBP System* (K111332, Jan 30, 2012; Product Codes: IYE, IWB, KPQ) – Elekta Ltd.
- *Calypso® 4D Localization System* (K060906, Jul 28, 2006 and K080726, May 14, 2008; Product Code IYE) – Calypso® Medical Technologies, Inc.

Intended Use / Indications for Use

Clarity® is indicated for use in external beam radiation therapy, to provide 3D ultrasound and hybrid imaging of soft-tissue anatomy to support radiation therapy simulation and planning, and to guide patient positioning prior to the delivery of treatment.

Clarity® may also be used with an Autoscan Probe for transperineal ultrasound (TPUS) imaging, to continuously monitor the motion of the prostate and to accurately guide patient positioning during the delivery of treatment (*i.e.*, intra-fractionally).

Device Description

Clarity® integrates medical diagnostic ultrasound and a real-time optical measurement system, which determines the 3D position of the ultrasound probes, to acquire and reconstruct 3D images of soft-tissue anatomy for use in external beam radiation therapy. During the course of treatment, non-ionizing 3D ultrasound imaging and optical tracking of couch position with *Clarity®* offers a non-invasive means for accurate localization of anatomical structures and patient positioning.

Clarity® comprises the following functional components:

- The *Clarity® Acquisition Station* is configured around an ultrasound console, which may be suspended from an articulated arm or mounted on a cart, with an integrated computer system and high-resolution touch screen. Acquisition stations are placed in the CT-Sim room (*Clarity® Sim*) and the treatment room (*Clarity® Guide*), with a ceiling-mounted optical measurement system and patient/couch position tracking tools.
- Each acquisition station is equipped with optically-tracked ultrasound probes; one or two hand-held probes for manual scanning and a motorized (Autoscan) probe for automated scanning. The user can select the probe and scanning method that is most appropriate for the given target anatomy and the patient's clinical presentation. The Autoscan probe includes a positioning apparatus that is specifically designed for transperineal imaging. The Autoscan probe remains in place during a CT-Sim scan and during radiation treatment; scanning is controlled from a remote console interface.
- A multimodality phantom is used for image calibration to the room's coordinate system that is defined by the corresponding room lasers, and for daily verification of system integrity for sub-millimeter target localization accuracy within each room.
- One or more dedicated workstation computer systems, connected to the hospital's local area network, are used for multimodality image fusion and review, soft-tissue structure definition, approval of patient positioning references, and review of treatment sessions.
- A dedicated central server computer system (typically combined with a workstation) houses the patient database and provides for interoperability with other imaging and treatment planning/simulation systems using the DICOM 3/RT protocol.

The *Clarity®* software is designed to step the user through a radiation therapy workflow or "course." Different courses are defined (*e.g.*, "Prostate", "General", "QC") to help classify patients in the database and to present the user with default choices and settings, tailored for the target anatomy (*e.g.*, prostate, bladder, liver, uterus & cervix, breast, head & neck) and daily QC. Such configurations include probe type, scan settings, contouring and assisted segmentation tools, and alert values for target misalignments.

At the time of CT-Simulation, a 3D ultrasound (3DUS) scan is acquired with the patient in the planning position. At the Workstation, the planning CT is imported and fused with the 3DUS, the structure of interest is defined, and a baseline positioning reference is approved. The 3DUS may be exported via DICOM to a third-party virtual simulator or treatment planning system (TPS).

In the treatment room, a 3DUS scan is used to determine target displacement relative to the baseline planning-day position, and to guide patient positioning prior to treatment.

When used with the Autoscan probe, *Clarity®* allows for continuous imaging of the prostate and surrounding anatomy to enable precise motion management during the delivery of treatment (*i.e.*, intra-fractionally).

To assist with the clinical workflow, *Clarity®* can be configured to send calculated couch shifts to the operator at the couch control user interface.

A web-based software interface is available with *Clarity®* for remote review of treatment session data and positioning references.

Comparison with Predicate Devices

With the release of software version 3.0, *Clarity®* offers 4D monitoring capability, expanding the indications for use of its predicate *Clarity® OBP System* (K111332). This capability for monitoring irradiation target motion and guiding patient positioning during treatment (*i.e.*, intra-fractionally) is substantially equivalent to that previously cleared for marketing with the *Calypso® 4D Localization System* (K060906, K080726). Both devices provide 3D localization information to assist with patient positioning prior to treatment and monitor the motion of the irradiation target during treatment, to alert the clinician if the target moves outside predefined limits.

The *Calypso® 4D Localization System* can monitor the position of the irradiation target during treatment by detecting electromagnetic signals from passive markers that have been previously implanted in or near the treatment target. 4D monitoring with *Clarity®* is based on automatic image analysis and contouring of soft-tissue structures, such as the prostate, in transperineal 3DUS images, which are continuously acquired during treatment. This is an expanded capability over the predicate *Clarity® OBP System*, in that the *Clarity®* software is now able to identify the soft-tissue target and track its motion over successive 3DUS images.

The differences in technological characteristics between *Clarity®* and the predicate devices do not raise different questions of safety and effectiveness.

Summary of Clinical & Non-Clinical Testing

Clarity® has been developed and tested in compliance with regulatory guidance and recognized consensus safety standards, including but not limited to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-37, and IEC 62304. Software and system verification and bench testing have been conducted under typical and reasonably foreseeable use error and boundary conditions.

Localization accuracy and precision specifications have been verified with multimodality phantoms. Clinical performance for prostate motion tracking was demonstrated in a side-by-side comparison with the *Calypso® 4D Localization System* and qualitative assessment of transperineal 3DUS images from continuous monitoring sessions with actual patients under simulated treatment conditions. Observational and performance data from a usability (simulated use) study with representative end-users and monitoring session data were evaluated to assure the safe and effective performance of critical tasks.

The test results demonstrate that *Clarity®* fulfills its design and risk management requirements, and is as safe and effective for its intended use as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 22, 2013

Elekta Ltd.
% Mr. George Papagiannis, M. Eng.
Regulatory Consultant, Medical Devices
2050 Bleury, Suite 200
Montreal, Quebec H3A 2J5
CANADA

Re: K121663
Trade/Device Name: Clarity®
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, IWB, and KPQ
Dated: November 14, 2012
Received: November 15, 2012

Dear Mr. Papagiannis:

This letter corrects our substantially equivalent letter of December 5, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121663

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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